FEB 1 3 2001

K002583
Page 1 of 10

510(k) Notification Summary
Safety and Effectiveness

February 9, 2001

Submitted by: VidaMed, Inc.
46107 Landing Parkway
Fremont, CA 94538
Contact: Tom McGaffigan
Phone: (510) 492-4960
FAX: (510) 413-1538

Product: TUNA Office System

Common Name: Electrosurgical Device

Equivalent Device(s): TUNA Cobra Hand Piece #K973366
Model 7600 Generator #K965061

Intended Use:
The TUNA Office System presented in this submission is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50cc.

Device Description:
The TUNA Office Cartridge and ProVu Handle work together to deliver RF energy from the TUNA Office System RF Generator (Model 7800). The TUNA Office Cartridge contains two needle electrodes, which are deployed at an angle of 90°. The needles can be deployed at 6 preset lengths, which vary between 12 and 22mm. The needles are insulated with Kynar at the base to protect the urethra during ablation of the prostatic tissue. Thermocouples are mounted on the tip of each needle to better control the temperature of the lesion during use. The disposable TUNA Office System Cartridge is attached to the TUNA ProVu reusable handle, containing the mechanism for the needle deployment and retraction. The TUNA Office System Cartridge only works with the TUNA Office System RF Generator (Model 7800)

Technological Characteristics
VidaMed currently markets the TUNA ProVu (Cobra was the name of used at time of 510(k) filing) Hand Piece, consisting of the ProVu disposable cartridge and the ProVu reusable handle. To provide energy, the ProVu RF generator (Model 7600) is connected via a cable to the ProVu Hand Piece, this constitutes the major components of the TUNA System. There is a non-sterile ground pad (model 7011), rectal probe (model 7003), and tubing set (model 6101) included with the disposable cartridge to complete the system. A telescope (model 8099) is also sold separately as part of the system. These items have not changed from the predicate device. The TUNA Office System Hand Piece and the TUNA Office System RF Generator will be marketed as part of the TUNA Office System. The new TUNA Office System represents a minor modification to the existing TUNA System. A comparison table of the new device and predicate devices has been included to show the difference between the devices.

Overview

In the current TUNA System the measurement of the lesion temperature is accomplished through a thermocouple placed in a Kynar plastic shield located approximately 20 mm away from the needle tip. The actual distance is dependent upon the selected needle length. Because the thermocouple is placed in the Kynar plastic shield and is located away from the tip of the needle, it has not possible to measure the actual needle temperature. For this reason, the current Tuna ProVu System raises the temperature of the needle over a 4 minute period gradually increasing the temperature to 53 degrees centigrade where it is then held for 1.5 minutes. The rise time of 4 minutes combined with a hold time of 1.5 minutes equals a total lesion time of 5.5 minutes. The measured temperatures are displayed graphically and digitally on the RF generator. In the predicate devices when the generator display is showing a needle temperature of 53 degrees C, the actual tip of the needle can actually be as high as 140 degrees C. This high temperature excursion can cause the tissue to dry up and deteriorate the electrical circuit between the patient and the device. As this electrical circuit deteriorates, the electrical impedance increases. Continued increases in electrical impedance can cause the electrical circuit to eventually deteriorate, resulting in the generator reaching its impedance limit. When the circuit deteriorates to this point the generator drops the power level in order to reduce the temperature. The electrical circuit can be re-established with this reduction in power. When reviewing actual patient data recorded when using the predicate device (graph A is an example) this data illustrated the system reducing the power levels in order to control the elevated electrical impedance spikes. Because of the placement of the thermocouple in the ProVu system, the power and impedance can fluctuate due to the relatively long period of time required for the system to react to rapid increases in temperature. This condition can be an irritation to the doctor performing the procedure and can reduce the amount of energy that is delivered during lesion formation. In order to prevent elevated impedance levels from shutting down the predicate system the temperature is raised slowly to 53 degrees C. In all predicate devices, if the temperature is raised too rapidly the system can quickly reach the impedance limit of the generator and interrupt the lesion formation. The TUNA Office system with its extremely rapid response time and the ability to measure temperatures inside the lesion being produced does not have this limitation.

Cartridge

VidaMeds goal in modifying the existing TUNA System was to eliminate the occurrence of high impedance shutdown during the TUNA procedure. In order to accomplish this goal, it was determined that measurement of the actual needle temperature inside the lesion was required. Because of this, the TUNA System cartridge was modified by relocating the thermocouples that measure lesion temperature from the plastic Kynar sheath to the inside of the tip of the needle. This change dictated a needle design change from solid Nickel Titanium wire to hollow Nickel Titanium tubing. With the thermocouple inside the tip of the needle, measurement of the lesion temperature could be accomplished in real time at the actual heat effected zone instead of 20 to 45 mm away as in the predicate device, (see graph C). In order to insure the same safety as the predicate device this new needle construction was rigorously tested. This new design incorporated two new additional materials inside the needle. These two materials are used to encapsulate and fill in the hollow needle assembly. Both materials have been tested for biocompatability and successfully passed these tests. The biocompatability testing was performed on sterilized cartridges and was performed per ISO 10993. The new needle construction was also tested in order to validate the ability to withstand considerable abuse to the same levels as the predicate device. The new needle construction passed these tests without breakage.

Software

A. The software that is installed on the TUNA Office System RF Generator was re-written from the assembly code of the predicate generator and converted into ANSI C code. This change was made in order to improve the ease of programming, ability to find and resolve software bugs, and to make it easier for generator maintenance. The programming industry has developed high level languages such as C that allow a programmer to review the lines of code in a more human readable format. The assembly language previously used by VidaMed was hard to maintain, difficult to debug and very difficult to read. Changes were very time consuming and required multiple iterations to assure compliance. By changing to ANSI C the programmer can write the code and any other programmer can read the code and understand the function. After compiling the code into assembly language each function was compared back to the original code for correctness. When all of the code was compiled and verified the final software was validated using the same protocol used on the predicate, Model 7600 generator. Safety testing was performed per IEC 601-1-4; software validation was performed per 120028-00. The new software successfully passed all validation and safety tests.

There were two basic modifications to the original software protocol; (a) we eliminated the review of the manual functions since they were removed from the accessible generator functions and (b) we changed the software protocol in order to validate the modified algorithm for needle temperature control.

A) The User interface was changed to eliminate the manual mode and make the needle algorithm come up to temperature faster. In the predicate Model 7600 generator a manual mode was incorporated to allow the physician to by-pass the automatic mode and set the temperature and rise time manually. This was included so the physician could switch to manual mode if high impedance problems were encountered during the creation of a lesion. Based on feedback from our users, it was determined; (I) the manual mode was very seldom used. (II) When the manual mode was used, the Physician ended up under treating the prostate due to a lack of understanding of how the system worked. (III) The user could not operate the system at all. Based on this feedback we removed the manual mode and improved the automatic mode to eliminate the high impedance problems. Since this function was removed verification and validation was not required. These changes make the procedure more intuitive and easier to use for the physician. The basic algorithms for safety and power generation have not been modified.

B) The nomogram in the TUNA Office device was changed to a PID (Proportional Integral Derivative) controller in order to take advantage of the new thermocouple placement. With the placement of the thermocouple at the tip of the needle (see Graph C) the thermocouple is now located in the same isothermal line as the needle tip. This placement now enables us to measure the actual needle temperatures inside the lesion. This is a significant improvement over the predicate devices where the thermocouple was placed in a position corresponding to a different isothermal line creating approximately a 40 to 50 degree C offset in temperature. With the new placement of the thermocouple we are now able to take advantage of the generators ability to poll and adjust the temperature of the needle 20 times a second. This ability allows the system to maintain the temperature of the needle at plus or minus 2 degrees centigrade during the procedure. With the ability to control temperature this accurately the occurrence of impedance shutdown is essentially eliminated. This accuracy also allows the system to decrease the period of time required to reach the target temperature of 110 degrees C, (see Graph B) without fear of experiencing an impedance related shutdown. The predicate device used a nomogram to increase temperature gradually over 4 minutes period to reach the target temperature of 53 degrees C (see graph B). This was necessary in order to reduce the occurrence of impedance problems.

Generator

The TUNA Office System RF Generator, the device that delivers the RF energy to the TUNA Office System Cartridge has been modified to remove the manual controls that were required on the Predicate device. The new generator and software were tested together using our RF controller software test protocol and successfully passed these tests.

System

The TUNA Office System cartridge will be manufactured with the same materials used currently in the TUNA ProVu System Cartridge, except for the addition of two new materials. These new materials underwent biocompatability testing conducted on a sterilized complete device and successfully passed. The TUNA ProVu reusable handle used to activate the TUNA Office System Cartridge will not change from the design of the predicate device. This design is compatible with the ProVu System and the TUNA Office System therefore, will be marketed as a part of both the TUNA Office System and the predicate device the TUNA ProVu System. To assure system equivalency between the TUNA Office System and the predicate device, lesion equivalency testing was completed and successfully passed. A summary of these tests is included below in the section entitled "Data Used to Suppot Substantial Equivalence". A side by side comparison of predicate TUNA systems to the TUNA Office system is presented in Tables A and B which also follow. Table A is entitled **Product Comparative charts TUNA system -- Cartridge**, Table B is entitled **Product Comparative charts RF Generator.**

Sterilization

Sterilization procedures for all of the components making up the TUNA Office System will remain the same as in the predicate device. The handle will continue to be made of stainless and aluminum, and is reusable. Cleaning and sterilization may be accomplished by several different validated methods, which are listed in the TUNA Office Systems User Guide, (SUG). Sterilization of the disposable cartridge will remain gamma sterilization as described in the TUNA Office System Instructions For Use (IFU), which is included in each package.

Data Used to Support Substantial Equivalence

There are five changes made which distinguish the TUNA Office System from the VTS ProVu / 7600 generator system. The changes and the appropriate test demonstrating substantial equivalence are listed in the chart below:

Type of Change	Test Performed for SE	Summary
1. Change in needle design replacing solid nickel titanium wire with hollow nickel titanium wire.	VidaMed PTCL 81(Protocol) Testing of reinforced hollow needle	Testing concluded the design of the hollow needle would hold up to the worst case user abuse as the predicate device. All tests were successfully passed.
2. Change software from Assembly language to ANSI C standard	1. Functional code verification of predicate software to assembly code compiled from re-written ANSI C code 2. Validation of Software by Test Report for RF controlled Software Document 120047 Rev.01	All functions were verified as equivalent during programming and Test Report Summary shows all functions were equal to predicate device. All tests were successfully passed.
3. Software Revision to remove manual mode and change needle temperature algorithm.	1.Test Report for RF Controlled Software Document 120047 Rev.01 (software Verification and Validation) 2. Electrical Safety 3. Hi Pot test	1.Test report validated input and output of model 7800 generator to be same as predicate model 7600) Passed 2. Electrical Safety test passed. 3. Hi Pot test passed
4. Reduction in lesion time from 5.5 minutes in the predicate device to 4 minutes in the TUNA Office System	Initial Lesion Equivalency Testing Between Cobra (ProVu) and TUNA Office	Tests conclude a 95% equivalency based on F-test and student T statistical analysis. Passed tests
5. Introduction of two new materials placed within the needle	Biocompatibility testing was performed independently and by the manufacture.	All biocompatability testing passed.

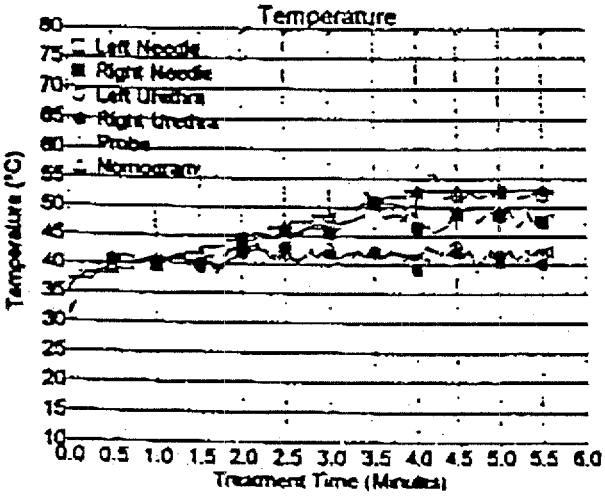
1. **Substantial Equivalence**
   A. Lesion Equivalence Testing was used by VidaMed to show equivalence between the TUNA ProVu System and the TUNA 3 System utilizing the Model 7600 (K965061) and Model 7205 (K960918) RF generators. To show equivalence between the Model 7800 Tuna Office System and the TUNA ProVu System VidaMed used the same Lesion Equivalency Testing protocols as used on the previous predicate devices. We have found in our clinical research that the size of the lesion is the best measure of determining system Equivalence.
   B. VidaMed's TUNA ProVu System and TUNA ProVu System RF Generator have been cleared for the treatment of symptomatic BPH in several 510(K)'s. The methods used in the prior submissions to establish substantial equivalence were repeated with the TUNA Office generator and cartridge system to assure substantial equivalence. The TUNA Office System Cartridge is a modification to the existing TUNA ProVu System Cartridge and shares similar features and function with corresponding devices distributed by VidaMed. Because of this VidaMed Inc. feels that Substantial Equivalence has been demonstrated.

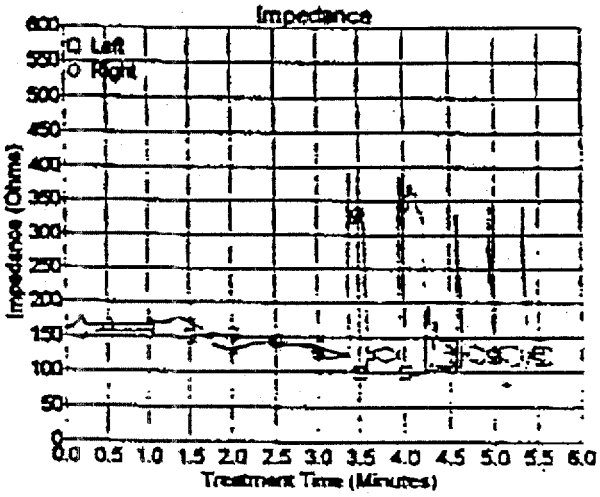
K002583
Page 6 of 10

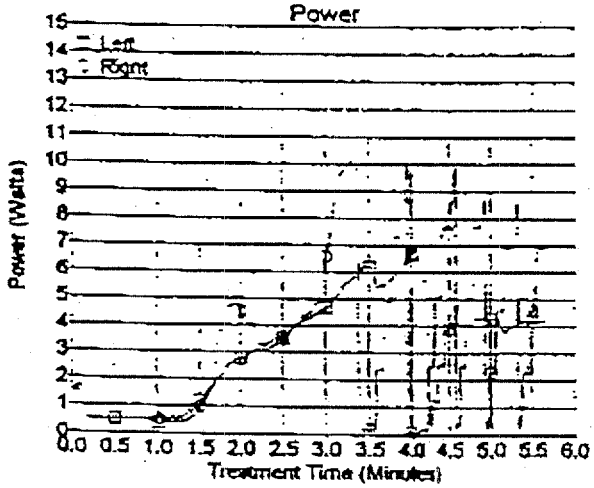
Subject: Apr-26-2000 13.12.15
Subject ID:
Date of Treatment: 04-26-00

Physician:
Facility:

Lesion: Lesion 3
Transverse: 61
Needle Length: 0
Shield Length: 0





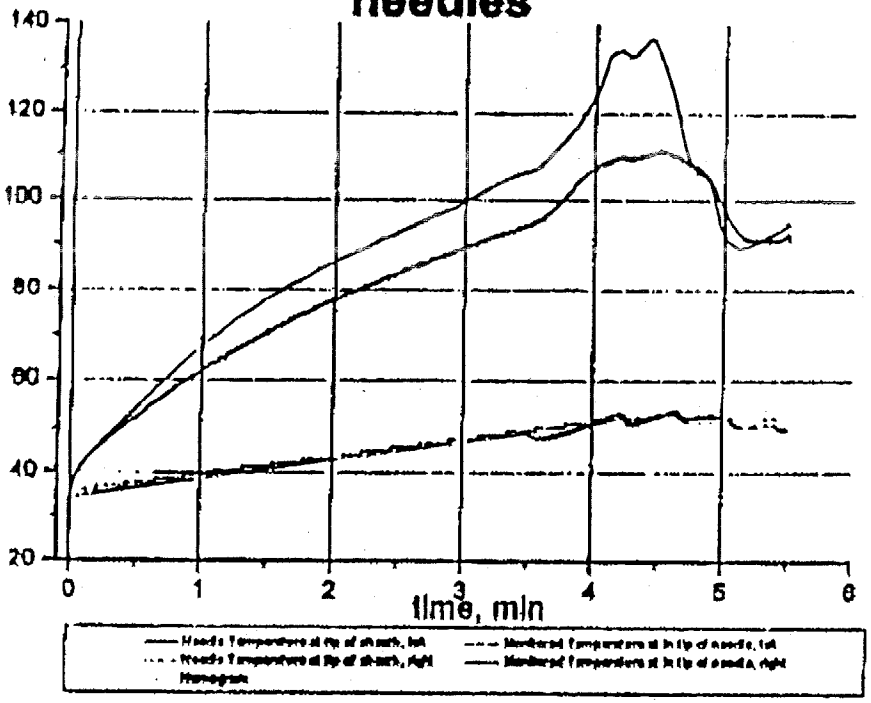


Time (min:sec)	Needle Temp (°C) Left	Needle Temp (°C) Right	Impedance (Ohms) Left	Impedance (Ohms) Right	Urethral Temp(°C) Left	Urethral Temp(°C) Right	Probe Temp(°C) Site 1	Probe Temp(°C) Site 2	Power Delivered (Watts) Left	Power Delivered (Watts) Right	Total Power (Joules) Left	Total Power (Joules) Right	Nomogram Temp(°C)
00:00	[illegible]	[illegible]	161	164	30.9	30.9	0.0	128.2	1.4	1.4	0000	0000	37.2
00:30	[illegible]	[illegible]	157	156	39.5	40.1	0.0	128.2	0.5	0.5	0024	0020	39.0
01:00	[illegible]	[illegible]	157	167	39.6	40.1	0.0	128.2	0.4	0.5	0035	0031	40.0
01:30	[illegible]	[illegible]	161	164	39.6	39.8	0.0	128.2	1.2	1.0	0055	0045	42.0
02:00	[illegible]	[illegible]	152	153	41.7	42.3	0.0	128.2	2.8	4.5	0117	0141	44.2
02:30	[illegible]	[illegible]	146	143	41.7	43.0	0.0	128.2	3.5	3.6	0207	0243	46.4
03:00	[illegible]	[illegible]	137	137	42.7	42.9	0.0	128.2	4.7	6.6	0332	0382	48.6
03:30	[illegible]	[illegible]	99	101	42.7	42.8	0.0	128.2	6.2	0.2	0498	0564	50.8
04:00	[illegible]	[illegible]	99	344	42.7	39.1	0.0	128.2	6.7	0.1	0675	0731	53.0
04:30	[illegible]	[illegible]	139	117	40.2	40.2	0.0	128.2	3.9	7.8	0791	0808	53.0
05:00	[illegible]	[illegible]	116	116	42.8	40.3	0.0	128.2	4.3	2.3	0916	0964	53.0
05:30	[illegible]	[illegible]	116	116	42.9	40.2	0.0	128.2	4.2	4.6	1036	1096	53.0

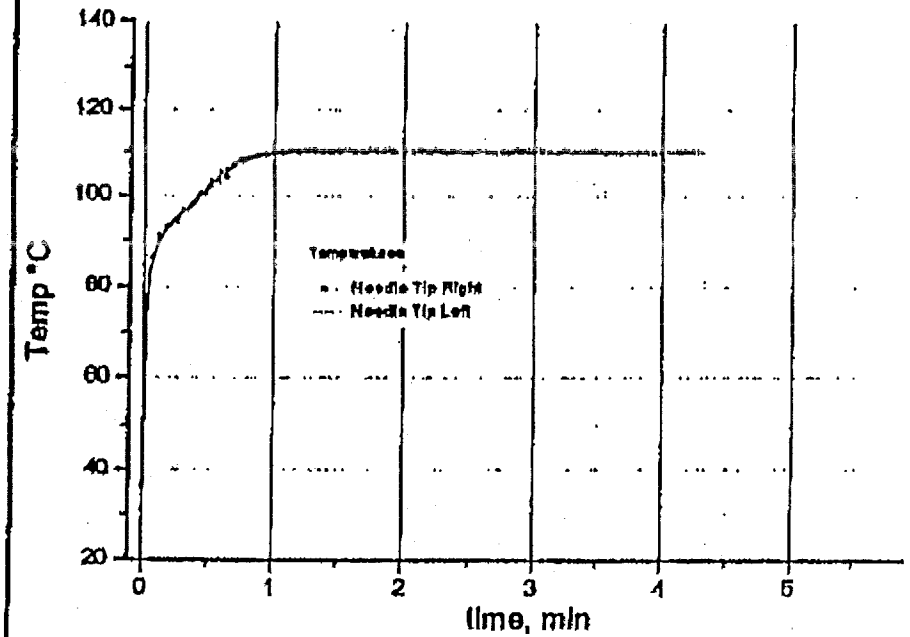
Graph A

Temperature Response

ProVu / 7600 system controlled by the needle thermocouples located in the sheath. Experimental temperature monitoring with additional thermocouple located in the tip of the needles



TUNA Office system controlled by the needle thermocouples located in the tip of hollow needles

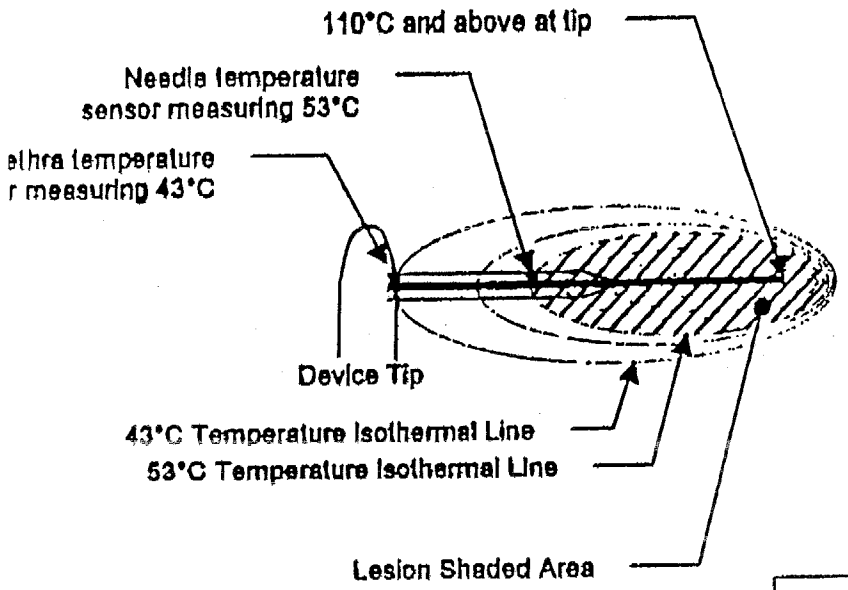


Graph B

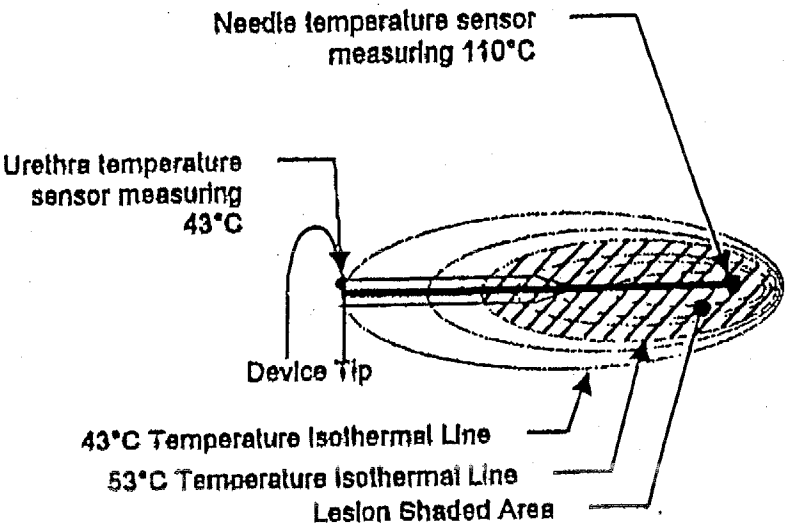
K002583
Page 7 of 10

Temperature Sensor Location

ProVu



Tuna Office



	ProVu	Tuna Office
Temperature at Needle tip	110°C and above	110±2°C
Temperature at sheath tip	53°C	Same as ProVu
Exposed deployed Needle Length	6-18mm	Same as ProVu
Needle Diameter	0.018in	Same as ProVu
Needle Length	12-22mm	Same as ProVu
Sheath Diameter	0.041in	Same as ProVu
Sheath Length	6mm	Same as ProVu

Graph C

Monday, November 20, 2000

K002583
Page 8 of 10

K002583
Page 9 of 10

TABLE A

Attachment F
A. Product Comparative Charts TUNA System-- Cartridge

Comparison of Intended Use/Design Features

VidaMed's TUNA System Models are provided to show the similarities of the TUNA Office System with TUNA ProVu System, TUNA 3 System and the TUNA 5 System.

Shaded areas identify change in Systems

VidaMed, TUNA Office System	VidaMed, TUNA ProVu System	VidaMed, TUNA 3 System (Model 6193)	VidaMed, TUNA 6 System
New Device: TUNA Office System TUNA Office System, a new Tradename may be chosen at chosen in the near future)	*Cleared in #K973366 (Cobra was the name submitted in the 510k)*	*Cleared in #K960918*	*Cleared in #K965199*
INDICATION:	INDICATION:	INDICATION:	INDICATION:
Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.	Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.	Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.	Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.
FEATURES:	FEATURES:	FEATURES:	FEATURES:
Needle: Nickel Titanium, hollow filled with Polyimide tubing and Loctite M-11 FLX Biocompatibility certification	Needle: Nickel Titanium	Needle: Nickel Titanium	Needle: Nickel Titanium
Needle Length: 12 – 22 mm	Needle Length: 12 – 22 mm	Needle Length: 0 – 22 mm	Needle Length: 14 – 22 mm
Number of Needles: 2	Number of Needles: 2	Number of Needles: 2	Number of Needles: 2
Needle Deployment Angle: 90°	Needle Deployment Angle: 90°	Needle Deployment Angle: 90°	Needle Deployment Angle: 0 - 90°
Sheath Size: 18.5 French	Sheath Size: 18.5 French	Sheath Size: 22 French	Sheath Size: 22 French
Sterile, disposable catheter	Sterile, disposable catheter	Sterile, disposable device	Sterile, disposable device
Reusable handle; TUNA ProVu System Reusable Handle, Stainless Steel And Anodized Aluminum	Reusable handle; TUNA ProVu System Reusable Handle, Stainless Steel And Anodized Aluminum	Integrated cartridge/handle	Integrated cartridge/handle
Optics: 0° commercially available 2.8 mm scope (Storz)	Optics: 0° commercially available 2.8 mm scope (Storz)	Optics: 0° for use with TUNA	Optics: 0° commercially available 4 mm scope
HEAT PROFILE:			
Lesion temperature at tip of needle: 110° C actual within +,- 2 degrees C	Peripheral lesion temperature is 53° (approximately 70-140° C at the tip)	Peripheral lesion temperature is 53° (approximately 70-140° C at the tip)	Peripheral lesion temperature is 53° (approximately 70-140° C at the tip)
POWER: 2 channels, 15 Watts each	POWER:2 channels, 15 Watts each	POWER:2 channels, 15 Watts each	POWER:2 channels, 15 Watts each
CONFIGURATION: Monopolar	CONFIGURATION: Monopolar	CONFIGURATION: Monopolar	CONFIGURATION: Monopolar
TEMP. RESPONSE TIME: .02 sec.	TEMP. RESPONSE TIME: 30 sec.	TEMP. RESPONSE TIME: 30 sec.	TEMP. RESPONSE TIME: 30 sec.

K002583
Page 10 of 10

TABLE B

Attachment F
B. Product Comparative Charts – RF Generator

Comparison of Intended Use/Design Features

VidaMed's TUNA System Models are provided to show the similarities of the VidaMed RF Generators. The TUNA Office System Generator (7800) works only with the TUNA Office System Cartridge. The TUNA ProVu System Generator (Model 7600) and the Model 7205 RF Generator operates the other Cartridges..

Shaded areas identify change in Systems

VidaMed, TUNA Office System RF Generator (Model 7800)	VidaMed, TUNA ProVu System RF Generator (Model 7600	VidaMed, RF Generator (Model 7205)
New Device: TUNA Office System RF Generator; a new name may be selected)	*Cleared in #K965061 (Cobra was the name submitted in the 510k)*	*Cleared in #K960918*
INDICATION:	**INDICATION:**	**INDICATION:**
Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.	Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in m age of 50 with prostate sizes between 20 a	Intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostat between 20 and 50 cc.
FEATURES:	**FEATURES:**	**FEATURES:**
Monitors Urethra and Needle Temperatures At tip of needles; displays on LED readouts	Monitors Urethra and Needle Temperatures At tip of needles; displays on LED readouts	Monitors Urethra and Needle temperatures; displays on LED readouts
Monitors and displays power output	Monitors and displays power output	Monitors and displays power output
HEAT PROFILE: Lésion temperature at tip of needle 110° C +-2 degrees	**HEAT PROFILE:** Peripheral lesion temperature at 53° (approximately 70-140° C at the tip)	**HEAT PROFILE:** Peripheral lesion temperature is 53° C (approximately 70-140° C at the tip)
POWER: 2 channels, 15 Watts ea.	**POWER:** 2 channels, 15 Watts ea.	**POWER:** 2 channels, 15 Watts ea.
CONFIGURATION: Monopolar	**CONFIGURATION:** Monopolar	**CONFIGURATION:** Monopolar
TEMP. RESPONSE TIME: .02 sec.	**TEMP. RESPONSE TIME:** .02 sec.	**TEMP. RESPONSE TIME:** .02 sec.
LESION FORMATION TIME: 4 minutes standard	**LESION FORMATION TIME:** 5.5 minutes standard	**LESION FORMATION TIME:** 5.5 minutes standard
SOFTWARE MODE: Automatic	**SOFTWARE MODE:** Automatic/Manual	**SOFTWARE MODE:** Automatic/Manual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Mr. Tom McGaffigan
Sr. Director, Research & Development
VidaMed®
46107 Landing Parkway
FREMONT CA 94538

Re: K002583
TUNA Office System
Dated: November 22, 2000
Received: November 28, 2000
Regulatory Class: II
21 CFR §876.4300/Procode: 78 KNS
Regulatory Class: II
21 CFR §878.4400/Procode: 79 GEI

Dear Mr. McGaffigan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATION FOR USE STATEMENT

K002583

510(k) Number (if known): N/A

Device Name:

TUNA Office System

Indication for Use:

The TUNA Office System presented in this submission is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002583